BURNS McDONNELL

WHITE PAPER / **USP 797 AND USP 800 STANDARDS**

PINPOINT A FLEXIBLE SOLUTION FOR SHIFTING STANDARDS

BY Doug Roeder, RA, NCARB, EDAC

New standards from the United States Pharmacopeial Convention (USP) will make regulations for hazardous and nonhazardous drug compounding more stringent. Until the standards are final, pharmacies may think building for the worst-case scenario is the only option to begin upgrades now. But a flexible, customized solution is possible with the right approach.

The new standards from USP represent a benchmark for how pharmacies store, prepare, transport and administer hazardous and nonhazardous drugs. USP 797 applies to all pharmacies that compound drugs and aims to minimize the risk of contaminating medicines during the compounding process. USP 800 helps protect healthcare workers who handle hazardous drugs.

Though USP 797 and USP 800 won't become official until December 1, 2019, the substantial facility upgrades they will most likely demand can be addressed now. The benefits of beginning the process now — increased time, flexibility in design and avoiding noncompliance — hinge on selecting the right tailored solution to mitigate risks without unnecessary over-building.

ONE SIZE DOESN'T FIT ALL

No one-size-fits-all solution exists to comply with these regulations. Each pharmacy will have unique needs based on its current facility design, specific operational needs and the state in which it is located. Avoiding expensive overbuilding relies on developing a precise strategy for a space's exact physical and operational needs.

Pharmacies located in hospital environments may present additional challenges because of the existing facility's limitations. Additional necessary square footage may be scarce. Moving walls and finding paths for proper ductwork and venting is time-consuming and messy. And, of course, pharmacies need to maintain consistent operations during the construction process.

Pharmacies have a long road to travel and they can't be expected to interpret and implement these requirements alone. A focus on insight, experience and an integrated approach is essential to optimize the investment.

- **Insight**: The USP standards are not yet final, but that doesn't mean intentions are unknown. The right design team has strategic partnerships with nationally recognized pharmacy consultants and an ear to the ground to anticipate the final adopted standard requirements.
- **Experience**: This is no job for a design team with minimal experience in designing critical pharmacy environments. Every design decision makes an impact. Some architects may recommend lofty ceilings for aesthetics but altering a ceiling height by mere inches can require a larger air handler to maintain required air change rates.
- **Integration**: Single-source delivery — where designers, engineers and contractors are integrated at all project stages — can complete projects up to 30 percent faster. That speed is vital when healthcare professionals are working amid construction to keep themselves and their patients safe.

STEPS TO COMPLIANCE — AND HEIGHTENED EFFICIENCY

A compounding pharmacy includes many components — shipping and receiving, storage, hazardous and nonhazardous drug compounding, anterooms, gowning areas and offices. Since each pharmacy serves a different patient population with diverse needs, volumes and procedures will vary widely.

1. Define Operational Needs

An effective process begins not with design but with understanding operational needs. This isn't just an opportunity to be compliant; it's a chance to make changes that help a pharmacy run more efficiently. Pharmacies must first ask and answer the right questions about procedures and equipment.

- What hazardous drugs does the facility handle according to USP guidelines?
- How long are drugs stored before they are administered?
- What type of hoods do pharmacy professionals use and prefer?
- What procedures are preferred for storing, unpacking, transferring and compounding drugs?
- Does the state enforce different standards than the USP requirements?

Answers to these and other questions drive changes to the physical environment. It's valuable to track the journey of hazardous and nonhazardous drugs through a pharmacy facility. An experienced partner can identify process changes that maximize operational efficiency while minimizing space requirements, all while keeping regulatory-driven changes in mind.

Some architects also maintain dedicated pharmacy planners and certification experts on staff. These specialists not only help develop design plans that support compliance, they can complete the certifications necessary to open a new or renovated facility.

2. Complete a Gap Analysis

The next step is a gap analysis of the facility and equipment — from mechanical, electrical and plumping systems to material surfaces and finishes. Building on the insight gleaned from step one, this analysis sets a foundation for an action plan that achieves both compliance and increased operational efficiency.

This step identifies risk areas and sets the stage for mitigation. Pharmacies are often "landlocked" in the middle of the hospital, so finding space to accommodate new regulations and introduce outside ventilation are common challenges. Ceiling heights are also an issue. A new vented exhaust hood might not fit into the space while still allowing sufficient space to clean around it.

Because USP 797 and USP 800 are measurably stricter than previous regulations, significant adjustments are necessary. The standards demand separate areas for the storage and compounding of hazardous drugs, when previously many pharmacies handled nonhazardous and hazardous drugs in the same room. Anteroom requirements have changed substantially. The expectations regarding pressurization, temperature and humidity control are also different, demanding changes to HVAC systems.

Cost has long been a critical barrier to compliance with these regulations. Understanding where a pharmacy falls short is critical to establishing an accurate budget for compliance efforts.

HOW USP 797 AND USP 800 COULD IMPACT THE BUILT ENVIRONMENT

Pharmacy spaces will need more square footage, HVAC system alterations and new equipment to accommodate these and other changes.

- **Buffer zones with proper airflow between compounding areas and non-compounding areas**
- **Deactivation and decontamination for all areas/ equipment where hazardous drugs are handled**
- **External venting for hazardous drug compounding areas**
- **Negative pressurization in compounding areas**
- **Neutral/normal pressurization in areas where hazardous drugs are unpacked**
- **Positive-pressure anterooms to a negative-pressure room**
- **Separate areas for unpacking, storage and compounding of hazardous drugs**
- **Separate primary engineering controls for sterile and nonsterile compounding**
- **Separate storage refrigerators for hazardous and nonhazardous drugs**

3. Design and Implement

An action plan emerges from all these considerations, encompassing the design, engineering and construction approach. Designing for the complexity of a complete compounding pharmacy demands flexibility and experience. Limited space drives the need for creativity: Perhaps the receiving and storage of drugs can be relocated to make room. Operational adjustments drive the need for adaptability: A new pass-through could greatly reduce the need to gown up and de-garb.

Throughout, the design team should consider current — and future — compliance standards. Because the regulatory environment is continually evolving, the design should provide enough flexibility to "future-proof" the space.

Before final design begins, the project team develops a budget, schedule and scope of work to align with the action plan. This full picture allows confidence in an actual complete project cost for board approval before the design document phase begins. If this step is overlooked, which happens all too often, final costs aren't known until bids are tallied, potentially increasing the project timeline.

By teaming with an integrated design-build partner, procurement of long-lead equipment can be done earlier and design and construction schedules can be integrated in a fast-track scenario — decreasing overall project schedules by up to 30 percent. This time savings is vital when healthcare professionals are trying to maintain clean and safe drug handling procedures in the midst of a messy construction zone.

No one-size-fits-all solution exists to comply with USP 797 and USP 800. Each pharmacy will have unique needs based on its current facility, specific operational needs and the state in which it's located. Avoiding expensive overbuilding relies on developing a precise strategy for a pharmacy's exact needs.

A RIGHT-SIZED SOLUTION

USP 797 and USP 800 will have a sweeping, far-reaching impact on the pharmacy community, and meeting compliance standards will be a lengthy and costly experience. Though the risk of designing a space to meet unfinalized requirements may add another layer of uncertainty, beginning the upgrade process now can benefit pharmacies that opt for an approach that addresses both compliance and operational excellence. A team able to assess and identify gaps and apply custom, right-sized solutions in the design, construction and operational phase can put pharmacies in the optimal position for compliance right now.

BIOGRAPHY

DOUG ROEDER, RA, NCARB, EDAC, is healthcare architecture practice leader and lead planner at Burns & McDonnell. He has spent more than 28 years focused on healthcare architecture, project management, design, planning and development. He leads complex projects from programming through post occupancy evaluation and certification.

ABOUT BURNS & McDONNELL

Burns & McDonnell is a family of companies bringing together an unmatched team of engineers, construction professionals, architects, planners, technologists and scientists to design and build our critical infrastructure. With an integrated construction and design mindset, we offer full-service capabilities with offices, globally. Founded in 1898, Burns & McDonnell is a 100% employee-owned company and proud to be on *Fortune*'s list of 100 Best Companies to Work For. For more information, visit **burnsmcd.com**.

03977-USP-0821